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August 12, 2021

VIA ECF

The Honorable Leonard P. Stark
United States District Court
for the District of Delaware
J. Caleb Boggs Federal Building
844 North King Street
Wilmington, DE 19801-3570

Re: *H. Lundbeck A/S, et al. v. Lupin Limited, et al.*, No. 18-cv-88

Dear Judge Stark:

I am writing on behalf of Defendants regarding the August 5, 2021 decision by the Federal Circuit in *GlaxoSmithKline LLC v. Teva Pharms. USA*, No. 18-1976, __ F.3d __ (Fed. Cir. 2021) (“*GSK II*”). During closing arguments (Tr. 2154; 2196), the Court asked Defendants for their views regarding the prior panel decision in that case. 976 F.3d 1347 (Fed. Cir. 2020), *vacated*, D.I. 181, No. 18-1976 (Fed. Cir. Feb. 9, 2021) (“*GSK I*”). Defendants also addressed *GSK I* in their post-trial brief on non-infringement. (D.I. 1047 at 86-87.) The holding in *GSK II*, like the holding in *GSK I*, has no impact on the present case.

First, the majority in *GSK II* upheld the jury verdict as supported by substantial evidence because it refused to “reweigh[] the evidence and find[] against GSK following the jury’s verdict in its favor.” *GSK II* at 19; *see also id.* at 11, 36 (“Teva asks us to supplant the role of the jury and reweigh evidence in its favor.”). The majority expressed no opinion on whether it would have reached the same conclusion as the jury on the evidence presented, but instead characterized their decision as a “narrow, case-specific review of substantial evidence” *Id.* at 10. By contrast, in the present case, the Court is the fact finder and is not bound by a jury verdict or the heightened JMOL standard of review that applied in *GSK II*.

Second, the facts in the present case are substantially different from *GSK II*. In *GSK II*, the majority upheld the jury verdict of induced infringement based on several pieces of evidence other than the proposed ANDA labels, including Teva’s press releases, product catalogs, and advertising and promotional activities. *E.g.*, *GSK II* at 24. No such evidence exists in the record before the Court in the instant case. The only materials generated by Defendants that Plaintiffs cite in support of their induced infringement allegations for the ’096 patent are the Defendants’ ANDA labels, which clearly show proper carve-outs. (D.I. 1057, pp. 73-81.) This is a critical difference from *GSK II*; the *GSK II* majority went out of its way to note that because “Teva distributed materials in addition to its labels, we do not have to decide in this case whether the labels alone are enough to establish causation.” *GSK II* at 37. As such, *GSK II* does not apply here where Plaintiffs have not identified any acts by Defendants that allegedly encourage infringement other than making their proposed ANDA labels available.



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Respectfully submitted,

/s/ Dominick T. Gattuso

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DTG/ram

cc: All Counsel of Record (via e-mail)